Registration for Medical Cannabis Independent Testing Laboratory



Maryland Department of Health Mental Hygiene Maryland Medical Cannabis Commission ("MMCC")

Registration for Medical Cannabis Independent Testing Laboratory "ITL"



Maryland Medical Cannabis Commission

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For additional information regarding the registration process, please contact:

Natalie M. LaPrade Medical Marijuana Commission

Department of Health and Mental Hygiene

For Registration Questions: dhmh.medicalcannabis.gov

Registration for Medical Cannabis Independent Testing Laboratory



REGISTRATION INFORMATION SHEET

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		Contact person for providing information, signing documents, or ensuring actions are taken regarding COMAR chapter 10.62.16.					
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	SIGNAT	URE:				DATE:	

Registration for Medical Cannabis Independent Testing Laboratory



A. Laboratory Employee Registration Form

Complete this form for every ITL employee. Use as many registrations forms as needed.

1. Laboratory Director Information					
Laboratory Director Name	Degree(s)	Employment Type Full Time Part Time			
Date of Birth					
2. Laboratory Supervisors and Manag	gers Information				
Supervisor or Manager Name	Degree(s)	Employment Type Full Time □ Part Time □			
Date of Birth					
3. Laboratory Employee(s)					
Employee Name	Degree(s)	Employment Type Full Time □ Part Time □			
Date of Birth					

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B. (1) Registration Submission Instructions

To register, an ITL shall:

- (1) Submit this completed ITL registration form as both a hard copy and an electronic copy in Microsoft Word format using a USB drive.
- (2) Submit a copy of the certificate of accreditation for the laboratory accompanied by the scope of accreditation;
- (3) Submit a registration for each ITL employee actually employed at the time of registration or intended to become employed; and
- (4) Pay the registration fee specified in COMAR 10.62.35.01 of \$100 per ITL, and \$200 for each ITL employee. All fees must be provided in the form of a check payable to the Maryland Medical Cannabis Commission.

B. (2) Provisional Registration Submission Instructions

Alternately, the ITL may apply for a provisional registration if it has not been issued a certificate of accreditation in Maryland. To register for a provisional registration, an ITL shall:

- (1) Submit a completed ITL registration form as specified above;
- (2) Submit a copy of the contract with an accreditation body for the Maryland-based laboratory seeking to register to become accredited, accompanied by a copy of the proposed scope of the accreditation; or
- (3) Submit evidence that the ITL has been accredited by the accreditation body in another jurisdiction;
- (4) Submit a registration for each ITL employee then intended to be employed; and
- (5) Pay the registration fee specified in COMAR 10.62.35.01 of \$100, and \$200 for each employee, in the form of a check payable to the Maryland Medical Cannabis Commission.

B. (3) Conversion of Provisional Registration to Regular Registration

Once a provisionally registered ITL has obtained a certificate of accreditation, it shall apply to be regularly registered, but:

- (1) The term of the registration may not exceed the term of the provisional registration; and
- (2) No additional registration fee need be paid for that term.

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C. Definitions

For the purpose of this registration, the following terms and definitions are used:

- (1) "Accreditation body" means a nonprofit, impartial organization that requires conformance to 17025 ISO/IEC requirements and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.
- (2) "Certificate of accreditation" means a certificate issued by an accrediting body for the ITL facility, entity or site to be registered in Maryland.
- (3) "Independent Testing Laboratory" or "ITL" means any facility, entity, or site in Maryland that offers or performs tests of medical cannabis or products containing medical cannabis, is independent of any entity that grows, processes or dispenses cannabis, and is recommended to comply with all of the below:
 - (a) Accredited as operating to ISO standard 17025 by an accreditation body:
 - (i) Operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011; and
 - (ii) That is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); and
 - (iii) That is independent from all other persons involved in the Maryland cannabis industry; and
 - (b) Registered with the Commission.
- (4) "Scope of accreditation" means a document issued by the accreditation body which describes the methodologies, range, and parameters for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.

For additional definitions, please see Md. Code, Health Gen §§13-3301- et seq.; and COMAR 10.62.01, et seq.

Registration for Medical Cannabis Independent Testing Laboratory



D. Laboratory Affirmation Section

The Registrant understands and agrees to the following:

	165	INO	IN/A
1. An ITL shall register with the Commission			
2. This Registration Form shall be complete in every material detail.			
3. To register, an ITL shall submit a completed ITL registration form.			
4. The Commission may disallow or terminate a registration if any part of the Registration Form contains a misstatement, omission, misrepresentation, or untruth.			
5. The Commission may request any additional information it deems necessary.			
6. The party seeking to register shall provide any additional information requested by the Commission, by the close of business of the 14th business day after the request has been received by the Registrant.			
7. If the party seeking to register does not provide the requested information within 14 business days, the Commission may deny the registration.			
8. To register, an ITL shall pay the registration fee specified in COMAR 10.62.35.01.			
9. To register, for a non-provisional license , an ITL shall submit a copy of the certification of accreditation accompanied by the scope of accreditation.			
10. To register, for a non-provisional license , an ITL shall submit detailed information regarding all laboratory employees and complete the			



	Yes	No	N/A
Laboratory Employee Registration Form.			
11. The Commission may issue a provisional license to an ITL that has not yet			
been issued a certification of accreditation in Maryland if the ITL:			
a. Submits detailed information regarding all laboratory employees and			
a completed ITL registration form;			
b. Pays the registration fee as specified in COMAR 10.62.35.01;			
c. Submits a copy of the contract with the accreditation body applying			
to become accredited, accompanied by a copy of the proposed			
scope of the accreditation;			
d. If accredited in another jurisdiction, the registrant will submit			
evidence the ITL has been accredited by the accreditation body in			
another jurisdiction; and			
e. Submits the name, address, and date of birth of each ITL employee			
and a copy of the application form completed by each ITL employee.			
12. Once it has obtained a certification of accreditation, a provisionally			
registered ITL shall apply to be registered, but:			
a. The term of the registration may not exceed the term of the			
provisional registration; and			
b. No additional registration fee need be paid for that term.			
13. The ITL shall require each employee to complete and execute the			



	Yes	No	N/A
Laboratory Employee Registration Form, as they are hired.			
14. The ITL shall establish and follow written procedures to verify the			
experience and education of laboratory employees, and to train every			
laboratory employee to completely carry out the employee's			
responsibilities.			
15. The ITL shall submit to the Commission the registration form for each ITL			
employee within 15 days after the date the ITL employee was hired.			
16. Upon termination of the association of a registered ITL employee with it,			
the ITL shall:			
a. Obtain any keys or other entry devices from the terminated ITL			
employee; and			
b. Ensure the terminated ITL employee can no longer gain access to the			
laboratory premises; and			
c. Within 1 business day of the termination of ITL employee, notify the			
Commission of the termination.			
17. The ITL shall notify the Commission within 1 business day after the ITL			
obtains notice of any kind that its accreditation has been denied, suspended			
or revoked.			
18. Registrant understands that the registration is valid for 2 years from the			
date it is issued by the Commission.			
19. The registration may be renewed by submitting to the Commission:			



	Yes	No	N/A
a. A copy of the ITL registration form;			
b. Payment of the registration fee in COMAR 10.62.35;			
c. Submission of copies of the most recent:			
i. Assessment from the accreditation body; and			
ii. Periodic review of the proficiency testing of the results			
obtained by the ITL.			
20. No ITL may handle, test, or analyze cannabis or cannabis products unless			
the ITL:			
a. Has been registered by the Commission;			
b. Is independent from all other persons and entities involved in the			
medical cannabis industry;			
c. Is accredited by an accreditation body or has a provisional			
registration from the Commission; and			
d. Has established standard operating procedures that provide for			
adequate chain of custody controls for samples transferred to the			
ITL for testing.			
21. The ITL shall follow the methodologies, ranges, and parameters which are			
contained in the scope of the accreditation for testing medical cannabis or			
products containing medical cannabis.			
22. The ITL will adopt a standard operating procedure to test medical cannabis			



	Yes	No	N/A
and medical cannabis infused products that are approved by an			
accreditation body that is a signatory to the International Laboratory			
Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.			
23. The ITL will obtain sufficient samples of each batch according to a			
statistically valid sampling method to conduct the necessary analyses.			
24. The ITL will analyze the samples according to:			
a. The most current version of the cannabis inflorescence monograph			
published by the American Herbal Pharmacopeia (AHP); or			
b. A scientifically valid methodology that is equal or superior to that of			
the AHP monograph.			
25. In the event of a test result for a sample which falls out of specification,			
the ITL shall:			
a. Follow its standard operating procedure to confirm or refute the	Ш	Ш	
original result;			
b. Issue a certificate of analysis; and			
c. Destroy the remains of the samples of medical cannabis after the			
analysis is completed.			
26. The ITI shall issue a contificate of analysis for each hotely with average time.			
26. The ITL shall issue a certificate of analysis for each batch, with supporting			
data, that reports:			
a. The chemical profile of the batch, and that the batch conforms to			
the specifications of the grower for the variety, for the following			



		Yes	No	N/A
compour	nds:			
ί. Δ	9-Tetrahydrocannabinol (THC);			
ii. Te	etrahydrocannabinolic Acid (THCA);			
iii. C	annabidiol (CBD);			
iv. C	annabidiolic Acid (CBDA); and			
v. Tl	he terpenes described in the most current version of the			
Ca	annabis inflorescence monograph published by the			
A	merican Herbal Pharmacopeia (AHP);			
vi. C	annabigerol (CBG); and			
vii. C	annabinol (CBN).			
	presence in the batch of the following contaminants does	Ш		
not excee	ed the levels as required by the AHP monograph:			
i. H	leavy metals, mercury, lead, cadmium, or arsenic;			
ii. Fo	oreign material such as hair, insects, or any similar or			
re	elated adulterant;			
iii. A	ny microbiological impurity, including:			
1.	. Total aerobic microbial count (TAMC);			
2.	. Total yeast mold count (TYMC);			
3.	. P. aeruginosa;			
4.	. Aspergillus spp.;			
5.	. S. aureus;			
6.	. Aflatoxin B1, B2, G1, and G2; and			
7.	. Ochratoxin A.; and			
8.	. Pesticide residue.			
c. Whether	the batch is within the specification of the grower for the			
	ristics of the variety regarding:			



	Yes	No	N/A
i. Odor;			
ii. Appearance;			
iii. Fineness; and			
iv. Moisture content.			
d. That in the batch the residual levels of volatile organic compounds			
(VOCs) are below the specifications as set by the United States			
Pharmacopeia (USP Chapter 467).			
27. An ITL shall conduct stability testing of samples provided by Licensed			
Growers at 6-month intervals.			
28. As a part of the stability testing, the ITL shall ensure the potency and purity			
of the sample.			
20 As a second of the stability has the ITI shall as a fide a second for a stability			
29. As a part of the stability testing, the ITL shall provide support for expiration	Ц		
dating for the sample.			
30. Submission of a Registration to register as an ITL irrevocably gives the	П		
Commission consent to conduct all inspections to ensure compliance with	_	_	
State law and regulations including inspection of:			
State law and regulations including inspection of.			
a. All premises of an ITL seeking to be registered; and			
b. All aspects of a registrant's operation to determine that the			
operation conforms to the terms of the registration.			
31. The Commission may conduct announced and unannounced inspections of			
the facilities of independent testing laboratories to determine compliance			



	Yes	NO	N/A
with statute and regulations.			
32. Failure by a registered ITL to provide the Commission with immediate			
access to any part of a premises, requested material, information, as part			
of an inspection may result in the imposition of a civil fine, suspension of			
or revocation of the registration.			
33. During an inspection, the Commission may:			
a. Review and make copies of all records.			
b. Enter any place, in which medical cannabis is held, tested,			
delivered, transported or otherwise disposed of.			
c. Inspect any records or files related to:			
i. Controls;			
ii. Facilities; and			
iii. Employee data.			
d. Question personnel present at the location.			
e. Review and make copies of all records.			
f. Enter any place, including a vehicle, in which medical cannabis is			
held, dispensed, sold, produced, tested, delivered, transported,			
manufactured or otherwise disposed of.			
g. Inspect all equipment, raw and processed material, containers and			
labeling, and all things therein including:			
i. Records;			



	Yes	No	N/A
ii. Files;			
iii. Financial data;			
iv. Sales data;			
v. Shipping data;			
vi. Pricing data;			
vii. Employee data;			
viii. Research;			
ix. Papers;			
x. Processes;			
xi. Controls; and			
xii. Facilities.			
h. Inventory any medical cannabis.			
i. Inspect any equipment, instruments, tools or machinery used to			
analyze:			
i. Medical cannabis;			
ii. Medical cannabis concentrate; or			
iii. Medical cannabis-infused product.			
j. Question personnel present at the location and any agent of the			
registrant.			
k. Obtain portions of any samples held by the laboratory for testing			
any:			
i. Cannabis;			
ii. Medical cannabis concentrate; or			
iii. Medical cannabis-infused product.			
iii. ivieuicai caimabis-iinuseu product.			



	Yes	No	N/A
34. In the event that an inspector has reasonable suspicion of an operational			
failure or of conditions that create a likelihood of diversion, contamination,			
or a risk to the public health, an inspector may:			
a. Suspend the activities of the registered premises;			
b. Order immediate evacuation of the premises and seal the entry			
door; or			
c. Notify the Maryland State Police if diversion is suspected.			
35. The inspector or Commission may notify the local fire department or police			
department, or appropriate regulatory agency, regarding a risk to public			
health and safety.			
36. If an inspection report contains a suggestion or demand for corrective			
action, the inspected entity shall within 10 business days from the delivery			
of the report:			
a. Respond in writing to every suggestion or demand for corrective			
action; and			
b. Set forth the plan for corrective action to be taken and the		П	
timetable for correction.			
timetable for correction.			
37. In the event the Commission finds there is a reasonable likelihood of			
diversion, contamination of medical cannabis, or any risk to the health of a			
patient or any other individual, after written notice and a hearing in			
accordance with the State Government Article, §§ 10-201-10-226,			
Annotated Code of Maryland, the Commission may:			
a. Impose a fine of up to \$10,000 per violation on a licensed grower,			
licensed processor, licensed dispensary or registered independent			



	Yes	No	N/A
testing laboratory;			
b. Deny the license or registration;			
c. Suspend the license, licensee, agent, employee, registration or			
registrant; or			
d. Revoke the licenses, licensee, agent, employee, registration or			
registrant.			
38. In the event the Commission finds there is a pattern of deviations from		Ш	
standard operating procedures or the terms set forth in the application or			
the license/registration but the pattern does not directly create a risk of			
endangering the health or safety of a patient, after written notice and a			
hearing in accordance with the State Government Article, §§ 10-201-10-			
226, Annotated Code of Maryland, the Commission may:			
a. Impose a fine of up to \$5,000 per violation on a licensed grower,			
licensed processor, licensed dispensary, or independent testing			
laboratory;			
b. Deny the license or registration;			
c. Suspend the license, registration, licensee, registrant, or agent; or			
d. Revoke the license or registration.			
39. In the event the Commission finds that a licensee, registrant, agent or			
employee violated a requirement of this subtitle, after written notice and a			
hearing in accordance with the State Government Article, §§ 10-201-10-			
226, Annotated Code of Maryland, the Commission may:			
a. Impose a fine of up to \$5,000 per violation on a licensed grower,			
licensed processor, licensed dispensary or independent testing			
laboratory;			
b. Suspend the license, registration, licensee, registrant, employee or			



	Yes	No	N/A
agent; or			
c. Revoke the license or registration.			

Registration for Medical Cannabis Independent Testing Laboratory



FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-EMPLOYEE

l,	, am an employee of a laboratory seeking to
register as an ITL with the State of Maryla Commission.	and's, Natalie M. LaPrade Medical Cannabis
investigation which, directly or indirectly consent to the Commission, the Maryland Commission to: (1) verify all information conduct a background investigation of make provided to any other jurisdiction see	sion ("Commission") may conduct a background, may include information about me. I irrevocably give d State Police, and persons authorized by the provided in the registration application documents; (2) e; and to have access to any and all information that I eeking a similar registration in that jurisdiction, as well risdiction during the course of any investigation that it
Commission any and all information about federal unit; any commercial or business	ize any of the following entities to release to the ut me that the Commission requests: any local, State or enterprise; any non-profit entity; any individual; or any sted information may be released in written, verbal,
the Commission, I expressly waive, releas	sing from the release of the requested information to se, discharge and forever hold harmless and agree to that releases the information to the Commission under
A photo, facsimile, or electronic copy of t effective as an original.	this signed and dated Authorization shall be equally as
Signature of Registrant	 Date
Printed Name of Registrant	



		NOTARY	
The undersi	gned, a Notary Public	in and for the County of	, in the State of
		rtifies that the above named individual ap	
		me or satisfactorily proved to be individua	
subscribed t	to the within instrume	ent and signed the Authorization and Not	ification.
This	dav of	, 20, and to wh	ich witness my hand
and seal.		,	,
		Notary Public	
		Printed Name	
Stamp or Se	eal		
Mv Commis	ssion Expires:	, 20	

Registration for Medical Cannabis Independent Testing Laboratory



FORM 2

AUTHORIZATION FOR RELEASE OF INFORMATION-BUSINESS ENTITY

Business Entity Name:	
Name of Authorized Representative Comple	eting Form:
	, am an Authorized representative of , ("Business Entity")
and I am empowered by the Business Entity	to execute this form on its behalf. Business Entity is ndent Testing Laboratory "ITL" Registration in the
registrant for a Medical Cannabis ITL. This is about the Business Entity. The Business Entity the Maryland State Police, and persons authorized in the registration approvided in the registration approvestigation of the Business Entity; and to Business Entity has provided to any other justiness Entity has provided to any other justiness.	plication documents; (2) conduct a background have access to any and all information that the urisdiction seeking a similar registration in that by that other jurisdiction during the course of any
release to the Commission any and all infor Commission requests: any local, State or fee	deral unit; any commercial or business enterprise; other public or private entity. The requested
the Commission, the Business Entity expres	g from the release of the requested information to sly waives, releases, discharges and forever holds entity, or individual that releases the information to Authorization.
A photo, facsimile, or electronic copy of this effective as an original.	s signed and dated Authorization shall be equally as
Signature of Authorized Representative	Date
Printed Name of Authorized Representative	



The undersigned, a Notary Public in and for the, certifies that the Representative of either known to me or satisfactorily proved to be within instrument and signed the Authorization	above named individual, as an Authorized, appeared in person, and before me, be individual whose name subscribed to the
This day of	
and seal.	
	Notary Public
	Printed Name
Stamp or Seal	
My Commission Expires:	, 20

Registration for Medical Cannabis Independent Testing Laboratory



FORM 3

Trade Secret & Financial Data Notification

is a registrant for a Medical Ca	nnabis ITL Registration.		
understands that the Commiss	sion is an entity of the State of Maryland		
and any documents or data that is submitted to the State of Maryland may be disclosed by the			
State pursuant to a Maryland Public Information Act	("MPIA") Request.		
While the MPIA permits certain exclusions from discle	osure, understands		
the State makes no guarantees or promises that such	data will not be disclosed.		
has reviewed the MPIA, as it is availa	ble online at		
http://www.lexisnexis.com/hottopics/mdcode.	understands that		
other helpful resources may be found at www.oag.sta	ate.md.us/Opengov.		
understands that the docume	ents or data it provides to the State of		
MPIA request.	may or may not be alsolosed parsaulte to a		
II Tequesti			
Signature of Person or Authorized Representative	Date		
Printed Name			

Authorized Representative- Printed

Registration for Medical Cannabis Independent Testing Laboratory



FORM 4

Business Interest Identification & Authorization Form , am an Authorized representative of , ("Business Entity") and I am empowered by the Business Entity to execute this form on its behalf. Business Entity is a registrant for a Medical Cannabis Independent Testing Laboratory "ITL" Registration in the State of Maryland. The Business Entity has either applied for, is currently, or has been previously registered, licensed or authorized to have contact with Cannabis in any form, in the following States or jurisdictions by the corresponding agency or authority. State & Name of Agency Type of Name of License or Registration # Registration/License Registration/License Business Entity hereby specifically grants to the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and its licensing agency or authority to confirm the information contained in the Registration, and affirms that as a registrant, it will adhere to all requirements in the law. Business Entity hereby specifically grants permission to the above listed States or jurisdictions and its licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the application, registration, licensing, or authorization to have contact with Cannabis in any form, including the following: (a) any denial, suspension, revocation or other sanction of the license, registration or authorization; (b) a copy of documentation so indicating; or (c)a statement that the registrant was so licensed or authorized and was never sanctioned. Authorized Representative- Signature Date

Registration for Medical Cannabis Independent Testing Laboratory



FORM 5

Business Entity Certification Statement Form

 Business Entity certifies that it, any other laboratory, Cannabis entity, or like entity, in which it holds or has held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation. Click here to enter text. 	☐ YES	□ NO
2. Business Entity is not a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed \$500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation. Click here to enter text.	☐ YES	□ NO
 Business Entity certifies that it is not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation. Click here to enter text. 	□ YES	□ NO
4. Business Entity affirms that if it has held any license or registration relating to Cannabis in another State, it has not been disciplined (including, but not limited to restricted, suspended, or terminated) by any State? If disciplined, provide a brief explanation. Click here to enter text.	□ YES	□ NO
5. Business Entity certifies that it has not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation. Click here to enter text.	☐ YES	□ NO
6. Business Entity acknowledges that it fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.);	☐ YES	□ NO
Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and		
Any activity regarding cannabis that does not comply with Maryland law		



or regulations is a violation of State law and could result				
prosecution, conviction, incarceration, fine, seizure of p				
of licenses or other privileges.				
Business Entity certifies its acknowledgement th Fees are non-refundable.	at Application	☐ YES	□ NO	
 8. Business Entity acknowledges that in filing a Regard a. The Commission is vested with broad discret Registrants; and b. The Commission's decisions in selecting the be final. 	ion to select the	☐ YES	□NO	
Signature of Authorized Representative Dat	 e			
Printed Name of Authorized Representative				
The undersigned, a Notary Public in and for the County of, in the State of, certifies that the above named Authorized Representative, appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.				
This day ofseal.	, 20, and to whic	ch witness my	hand and	
	Notary Public			
	Printed Name			
Stamp or Seal				
My Commission Expires:	, 20			

